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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 3, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 3

William R. Cammack
President
C&H Chemical, Inc.
222 Starkey Street
St. Paul, Minnesota 55107

Dear Mr. Cammack:

During a recent inspection of your veterinary drug manufacturing located in St. Paul, MN, our investigator found significant deviations from the Good Manufacturing Practice for Finished Pharmaceuticals (CGMP) regulations [Title 21, Code of Federal Regulations, Part 211 (21 CFR 211)]. Such deviations cause veterinary drugs manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigations found the following deviations:

1. For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release [21 CFR 211.165(a)]. There is no testing for identity and strength of the following products: CHG Barricade Chlorhexidine TD, Pre and Post TD Chlorhexidine, and Non-Iodine TD (Linear Dodecyl Benzene Sulfonic Acid.)

2. The accuracy, sensitivity, specificity and reproducibility of test methods employed by the firm shall be established and documented [21 CFR 211.165(e)]. There is no documentation of the method used for iodine containing teat dips meeting this requirement.

3. Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assay, as follows: The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards [21 CFR 211.194(a)(8)]. A second person is not checking and signing and laboratory/test records.

4. Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to ensure that the reprocessed batches will conform with all established standards, specifications and characteristics [21 CFR 211.115(a)]. There are no written procedures.

5. Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product [21 CFR 211.67(b)]. There are no written procedures for the water system.

6. Records shall be kept of maintenance, cleaning, sanitizing and inspection of equipment [21 CFR 211.67(c)]. There are no records for the water system and other major equipment.

7. At least one test shall be conducted to verify the identity of each component of a drug product. Specific identity tests, if they exist, shall be used [21 CFR 211.84(d)(1)]. No *specific* tests are used for chlorhexidine or iodine.

8. Weighing, measuring or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that: (1) The

component was released by the quality control unit; (2) The weight or measure is correct as stated in the batch production records; (3) The containers are properly identified. Each component shall be added to the batch by one person and verified by a second person [21 CFR 211.10(c) and (d)]. There is no second person checking the weight/volume of the components added to a formulation and no second person checking that the components were added to a formulation.

9. Each lot of a component, drug product container or closure that is liable to microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use [21 CFR 211.84(d)(6)]. No microbiological tests have ever been run on the water used in the formulations.

The above is not intended to be an all-inclusive list of violations. Please refer to the form FDA-483 issued by the investigator at the conclusion of the inspection for a complete list. As a manufacturer of veterinary drugs you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Enclosed is a copy of 21 CFR 211.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

RPS/ccl

Enclosure: 21 CFR 211

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